TECHNOIMPLANT

Brushless

USER MANUAL

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TECHNOIMPLANT Brushless

SURGICAL IMPLANTOLOGY MICROMOTOR WITH PHYSIODISPENSER

SPEED AND TORQUE MICROPROCESSOR CONTROLLED

CE 0476

ECC 93/42: CLASS IIa

1. INTRODUCTION

Your new "**Technoimplant *Brushless***" is a surgical micromotor with physiodispenser that combines simplicity to high performance.
It is entirely designed and built by RTC Sistemi both for hardware and software.
Equipped with a unique design pedal of one centimetre thickness that represents an absolute novelty.
It uses a brushless induction autoclavable micromotor that reaches the speed of 40.000 RPM (Revolution Per Minute), to which can be coupled every type E contrangle that follows the standard ISO 3964.
The peristaltic pump is mounted externally from the central unit with the purpose to prevent any possible flooding of the equipmentt in case of break of the irrigation pipe.
The pump, entirely built by RTC Sistemi, in a simple approach, entirely of metal and this assures a great sturdiness. It is of the type provided with a spring-loaded tubing bed that ensures perfect tightness of the silicone tube with the pump off.
The pressure operated by the spring can be regulated simply and easily by hand in such a way that the perfect holding of the liquid can be assured.
The pedal is extremely innovative denominated 'solid state' because it doesn't have any mechanical moving element, while allowing all the functions of the other pedals. Built on a strong stainless steel plate and oval-shaped for elegance of design, covered entirely with a resilient synthetic rubber which makes it resistant to any leaking fluids, it rises only10 mm from the floor, equipped with a force sensor that determines the speed of the motor in progressive action according to the pressure practiced with the foot.

2. SAFETY PRECAUTIONS

The device must be used only by competent dentists qualified in implantology.
The device meets the requirements of the applicable electromagnetic compatibility standards fixed by the norms in force.
However the user should ensure that a possible interference doesn't provoke a risk in certain equipments in the proximities of the tool. It could for instance occur interferences on cardiac pacemaker or other similar devices.

1) RTC Sistemi cannot accept responsibility direct or indirect for lesions or resultant damages from improper uses, consequential particularly from the not observance of the operational instructions or maintenance of the product.

2) Before using the equipment read this manual carefully to become completely attentive to all operating instructions.

3)The component motor-cable-connector and autoclavable micromotor support is furnished not-sterile. Therefore before the use sterilization is recommended.

4) The use of accessories of other builders is exclusively left to the responsibility of the operator.

5) Servicing must be performed by RTC Sistemi or by authorized personnel.

6) Operating with this unity follow these guidelines:
- never touch drills, burs, or other handpiece tips when they are still rotating.
- insert contrangles when the motor has stopped running.

7) Do not install the instrument where there is a risk of an explosion. This device is not for operating in presence of inflammable anaesthetics or gases.

8) With the purpose to assure the best accuracy of torque and speed of the motor, it is recommended that calibration is performed every change of contrangle.

9) Contrangles have intrinsic inefficiencies that can lead to torque variations. If it is desired a further and more accurate verification of the torque it is suggested to use a torque wrench.

10) Always follow the instructions of the producers that accompany the contrangle with respect to the maximum allowed speed, couple, direction reverse forward and other instructions of use.

11) The system of irrigation is conceived for use with a saline solution or sterile water. Always follow the instructions recommended by the implants manufacturers.

12) Connect line power cable to a plug provided with earth protection.

13) The motor is sensitive to shock and may be damaged if allowed to fall on a hard surface.

14) Do not lubricate the motor. Lubricate only the contrangle and make sure that the lubricant doesn't penetrate into the motor.

15) Do not abruptly fold up the motor cable for placing it in autoclave.

3. NOTICE

This symbol warns the user to refer to the manual.

Technoimplant is a surgical implantology micromotor with physiodispenser suitable for every type of dental implant, burs and handpieces with INTRA plug, provided they are CE marked according to UE directive 93/ 42 Medical Device. Its usage is allowed only in a hospital environment, in clinics and dental surgeries. It should be used only by expert qualified dentistry physicians.

The manufacturer accepts no responsibility in the event of: a) actions or repairs carried out by persons not authorized by the manufacturer or importer, b) use on an electrical system not incompliance with the terms of regulation CEI 64-4, c) any use different from the one specified in this manual.

4. TECHNICAL DATA

Manufacturer	RTC Sistemi s.n.c. - PRATO - ITALY
Name	TECHNOIMPLANT Brushless
Dimension	255 x 255 x 110 mm
Material	Central unit: ABS and aluminium Motor case: aluminium
Weight	2.6 kg
Torque Max. of the motor	43.8 mNm
Noise	<65 dB A
Supply voltage	AC 230 / 115 V ± 10% 50/60 Hz
Power	80 VA
Fuse 230 V	Size: 5 x 20 mm 2 x 0.8 A T (Slo-Blo)
Fuse 115 V	Size: 5 x 20 mm 2 x 1.6 AT (Slo-Blo)
Type	BF
Classification	Medical device: IIa , Rule IX , 93/42 CEE
Use	Intermittent: 30 s ON and 10 s OFF
Temperature of use	From +15 °C to +40 °C Not suitable for use in the presence of inflammable anaesthetics or oxygen
Storage temperature	From +5 °C to +70 °C
Temperature of use	From +15 °C to +40 °C

5. Package contents

1) **CENTRAL UNIT**
2) **MULTIFUNCTION PEDAL**
3) **AUTOCLAVABLE MICROMOTOR WITH CABLE AND CONNECTOR**
4) **PHYSIOLOGICAL SOLUTION SUPPORT ROD (stainless steel).**
5) **AUTOCLAVABLE MICROMOTOR SUPPORT**
6) **SINGLE USE STERILE IRRIGATION KIT one way (3 pieces)**
7) **PROTECTION CAP FOR AUTOCLAVE STERILIZATION OF MICROMOTOR**
8) **POWER SUPPLY CORD**

6. DESCRIPTION

6.1 FRONT PANEL

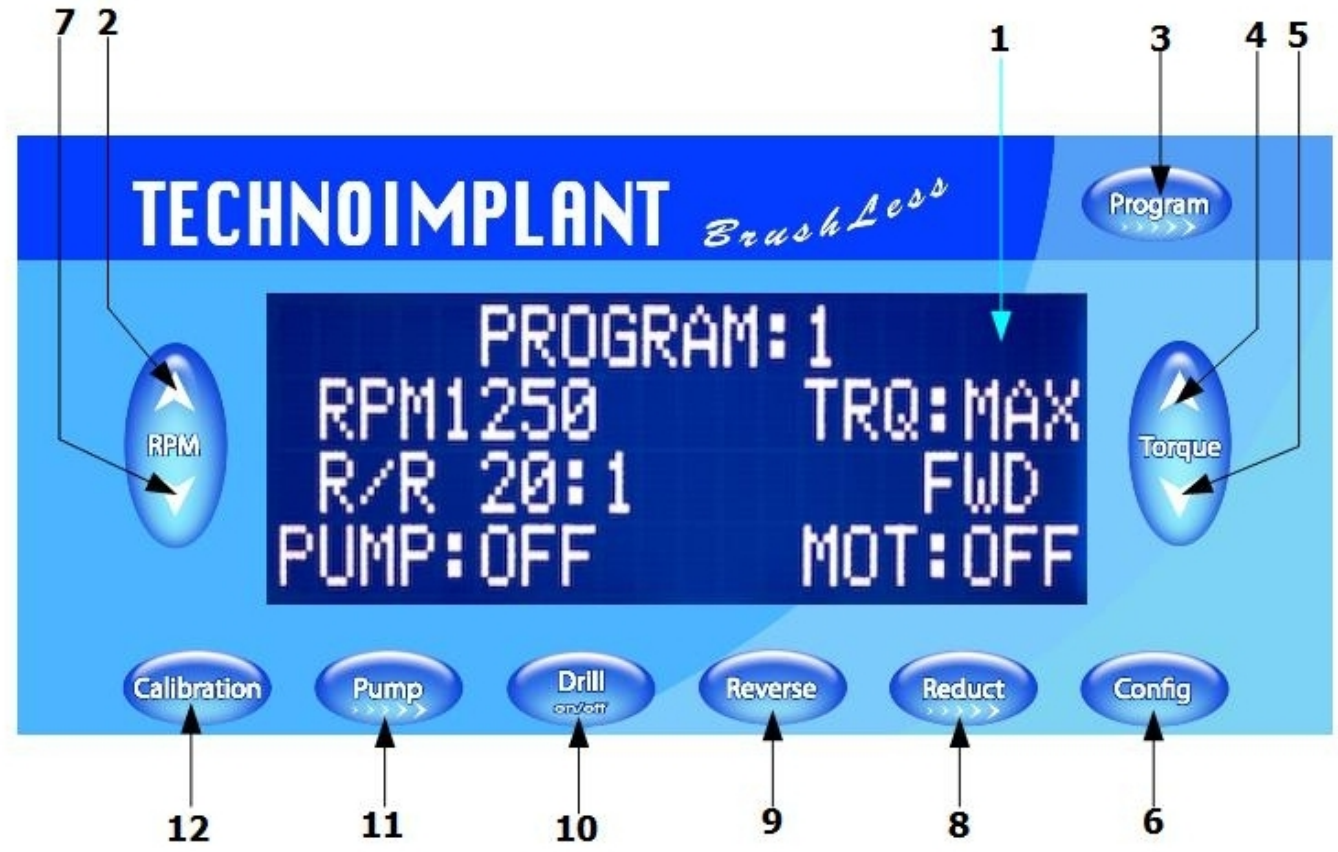

Fig. 1

TECHNOIMPLANT Brushless has two program management modes: Program Mode and Phase Mode, selectable from **Config** button.

The five programs mode: this is the default mode.
In PROGRAM Mode there is the choice of 5 programs that can be customized with different parameters (Torque, Speed, Contrangle reduction ratio, Irrigation flow and Rotation direction).

The PHASE mode: In the PHASE mode, within each of the 5 programs selected by the front panel PROGRAM button, there are 4 phases which can be selected by the upper central button (2) of the pedal, obtaining in this way 4 working phases for each of the 5 programs.
To each of the 5 programs may be matched a particular implant, and the 4 phases may be programmed for instance as Pre-drilling, Drilling, Tapping or Screwing.
20 programs are thus available for the user.

6.2 CONTROL PANEL FUNCTIONS

1. **DISPLAY** : easily read alphanumeric multifunction screen, to visualize all functions on 4 lines.

2. **RPM UP:** to set the micromotor speed, with scrolling up of 21 values: from 400 to 40000 rpm with reduction rate 1:1; from 25 to 2500 rpm with reduction rate 16:1; from 20 to 2000 rpm with reduction rate 20:1; from 12 to 1250 rpm with reduction rate 32:1, from 6 to 625 rpm with reduction rate 64:1 and from 5 to 500 with reduction rate 80:1.

3. **PROGRAM**: to set 5 programs with scrolling up values: 1-2-3-4-5.
For each program the following can be set: reduction rate, rpm, torque, peristaltic pump speed, clockwise and anti-clockwise direction.

4./5. **TORQUE**: to set the micromotor torque value by scrolling it up and down. With the reduction rate 20:1 24 values can be selected from 3 to 69 Ncm in 3 Ncm steps.
In the MAX position there is no torque limitation.

> Regarding torque, Technoimplant Brushless is adusted with a W&H 20:1 contrangle, therefore the best precision is obtained with a W&H Contrangle 20:1 or equivalent.

6.**CONFIG**: It shows the configuration menu. It is possible to choose 4 combinations between "Phase" and "Rheostat" pressing the **Program** button. As soon as the wanted combination is set press again the **Config** button and data will be memorized and the configuration menu will be leaved.

7. **RPM DOWN:** to set the micromotor speed by scrolling down the values.

8. **REDUCT**: to set the contrangle reduction or multiplication rate. Available reduction rates are: 1 :1, 16:1, 20:1, 20:1WH, 32:1, 64:1 and 80:1.

9. **REVERSE**: to set the micromotor clockwise or anticlockwise rotation. At first pushing the micromotor is ready to run anticlockwise at the preset speed. A beep warns that the micromotor is set in "REVERSE", and "REW" appears on the LCD display.

10. **DRILL**: Micromotor On/Off.

11. **PUMP**: to set the peristaltic pump flow. 3 values available:
min, mid, Max, Off, with Off = No flow.

12.**CALIBRATION**: to calibrate the contrangle.

N.B.: To reset the instrument software

Switch Off and than switch on the unit while pressing the "Program" button on the keyboard.
After resetting the software, all the programs will show the manufacturer's default settings.

6.3 REAR PANEL and PERISTALTIC PUMP

Rear panel is shown in the following figures: with the spring closed (Fig.2) and with the spring open (Fig.3)

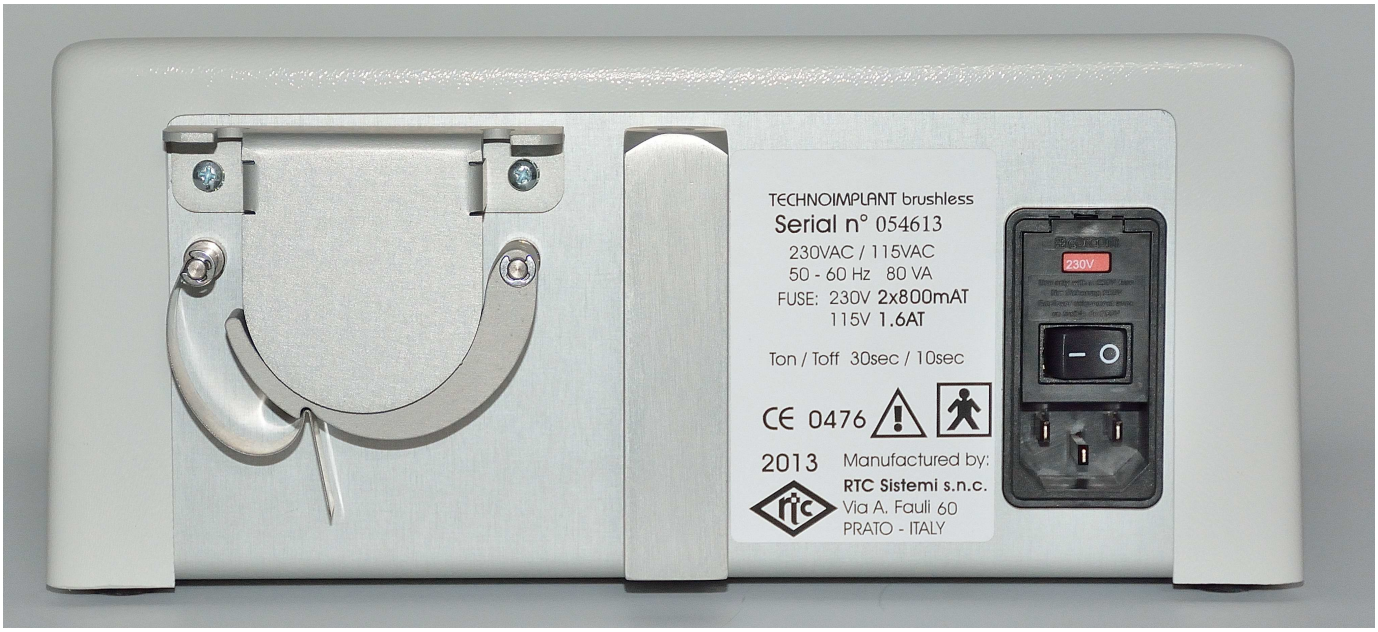

Fig.2

Fig.3

To insert the irrigation set tube, disengage the spring from the tubing bed and position it as shown in the pictures.

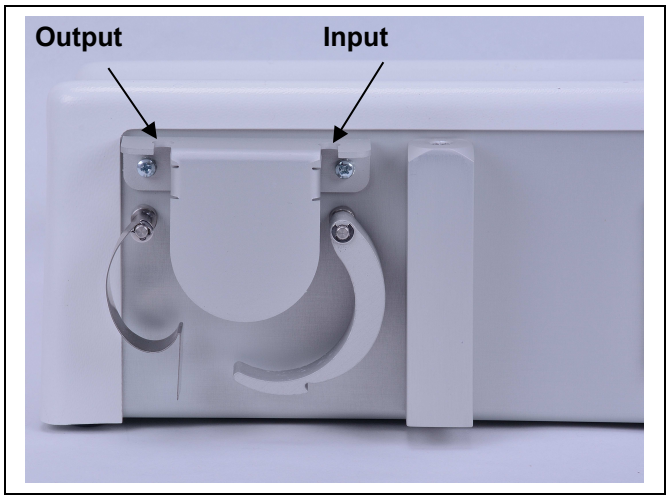

Fig.4

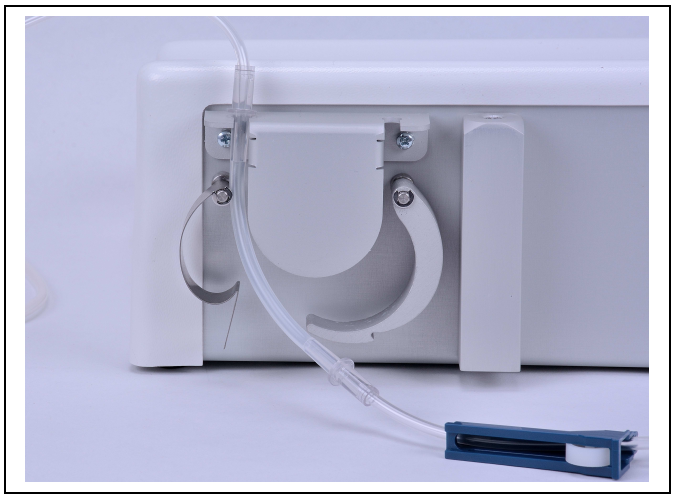

Fig.5

Fig.6

Fig.7

6.4 PEDAL

Fig.8

1. To sets the peristaltic pump flow. 4 values are available: 20, 30, 45, and 60 ml/min. Off = No flow

2. **In the five programs mode:** scroll the 5 available programs 1, 2, 3, 4 and 5. **In the PHASE mode:** scroll PHASE, 1, 2, 3 and 4 inside the selected program.

3. To set the micromotor clockwise or anticlockwise rotation. At first push the micromotor is ready to run anticlockwise at the preset speed. A beep warns that the micromotor is set in "REVERSE", and "REW" appears on the LCD display.

4. To Start the peristaltic pump and the motor with rheostatic effect.

7. INSTALLATION

The unopened package can be stored at a temperature from 5 °C (41 °F) to 65 °C (149 °F), with relative humidity below 90%. Open the package by cutting the adhesive tape, remove first any packaging materials, then the instrument and its accessories, and place the unit on a flat surface. Allow at least 150 mm free space around the unit for ventilation.
Before installing, make sure no damage has occurred in transit. Any such damage should be reported to the dealer within 24 hours from receipt.
Verify the contents according to paragraph 5. PACKAGE CONTENTS.

When installing Technoimplant, please observe the following.

1. This equipment must be used only by specialized personnel. Do not allow unauthorized persons to touch the unit or play with it, nor to use it for any unapproved purposes.
2. Place the unit away from any direct or indirect heat source.
3. Avoid humid environments or contact with any liquids.
4. Allow air to circulate around the unit to cool it.
5. It is forbidden and dangerous to modify in any way this equipment; in this case RTC Sistemi will not be responsible for any eventual damages.

Environmental conditions

- Altitude : below 2000 m (6500 ft)
- Temperature : 18 - 40 °C (64 - 104 °F)
- Relative Humidity : < 80%
- Mains variations should not exceed +/- 10% of nominal voltage
- The Micromotor should not be working continuously for more than 3 minutes.

8. CONNECTIONS

1. Set the supply voltage in accordance with the local supply (Fig. 2 Voltage selector).
2. Connect the power supply cord.
3. Connect the motor plug.
4. Connect the pedal plug.
5. Insert the physiological solution support rod.
6. Insert the physiological solution.
7. Insert the peristaltic pump irrigation set as described on page 10.
8. Switch on the unit (0=Off – I=On) (Fig. 2).

9. USE

When switching on the instrument the parameters are the same for every program (default parameters):

- Reduction Rate= 20:1
- RPM = 2000
- Forward
- Torque = Max
- Peristaltic pump flow: MAX

The unit – in its default state - is ready to set 5 programs: each program includes the following functions, which will be automatically performed when the appropriate program number is selected:

- Reduction Rate
- RPM
- Forward/Reverse
- Torque
- Peristaltic pump flow rate
- Clockwise and anti-clockwise rotation

9.1. To select the preferred configuration.
As we have said in the "Control,Panel Functions", TECHNOIMPLANT Brushless gives two modes in the program management and the possibility to use or not the Rheastat effect on starting the motor from the pedal.
Pressing the **Config** button, the configuration menu appears on the display. At this point pressing the **Program** button it is possible to choose one of the four combinations between Rheostat and Phases mode.

Rheostat ON and Phases OFF	Rheostat OFF and Phases OFF
Rheostat ON and Phases ON	Rheostat OFF and Phases ON

As soon as the desired combination is obtained, press the **Config** button again to memorize the
selected choice and exit the configuration menu.

9.2.To select the program
Press "Program" on the keyboard, or the specific button on the pedal (2 on Fig. 3): 5 programs are scrolling up.

9.3. To select the reduction rate
Press "REDUCT" on the keyboard. Available reduction rates are:

1:1 - 16:1 – 20:1 – 20:1 Wh – 32:1 - 64:1 - 80:1 .

(Reduction rate 20:1Wh is for the W&H models e.g. WI-75 E/KM model or equivalent).

9.4. To select the rpm
Press "RPM" on the keyboard to increase or decrease the rpm. The speeds will appear on the display (by keeping it pressed they scroll quickly, otherwise step by step). It is possible to scroll 21 values from 400 to 40000 rpm with reduction rate 1:1, from 25 to 2500 rpm with reduction rate 16:1; from 20 to 2000 rpm with reduction rate 20:1; from 12 to 1250 rpm with reduction rate 32:1, from 6 to 625 rpm with reduction rate 64:1 and from 5 to 500 with reduction rate 80:1.

9.5. To select the torque

Press "Torque" on the keyboard to increase or decrease the value. The torque values will appear on the display (by keeping it pressed they scroll quickly, otherwise step by step). It is possible to scroll 24 values from 3 to 69 Ncm (in steps of 3 Ncm) with the reduction rate 20:1. In the MAX position there is no limiting torque.

Torque vs. Motor speed	
Torque	Max Motor speed
From 3 to 12 Ncm	1250 RPM
From 15 to 36 Ncm	1750 RPM
From 39 to 69 Ncm	2000 RPM

9.6. To select the peristaltic pump flow

Press "Pump" on the keyboard, or the specific button on the pedal (1 on Fig. 3). 3 different peristaltic pump flows are available: min, mid, Max, Off. Off = no flow.

9.7. To select Forward/Reverse

Press "Reverse" on the keyboard, or the specific button on the pedal (3 on Fig 3). A beep warns that the micromotor is set in "REVERSE", and "REV" appears on the LCD display.

9.8. Contrangle calibration

The resistance of a contrangle varies according to the contrangle model, its age and condition, the degree of wear on the contrangle gear, and so on. This function recognizes the level of resistance and calibrates the micromotor so that it will rotate to the specific speed and torque required.

- Insert the contrangle on the micromotor.
- Press "Calibration" on the keyboard.

The motor will automatically start to run. When the resistance diagnosis is completed, the micromotor will stop. The contrangle calibration is now completed.
N.B.: Any drill must be removed from the contrangle before starting the calibration process.

9.9. To start the motor

Press "Drill" on the keyboard, or the specific button on the pedal (4 on Fig 8).

10. CLEANING

Clean the external surfaces of the case using a clean soft cloth dampened with water and/or alcohol, or another disinfectant.
Avoid any splashes: the instrument case is not watertight.

11. STERILIZATION

STERILISABLE PARTS
- Micromotor and cable
- Physiological solution rod
- Micromotor stand

STERILISING :
- Apparatus = water or chemical vapour autoclave.
- Time = 40 min. at 134 °C (273 °F), 2 bar.

Where possible we suggest to sterilize with BIDISTILLED WATER at 121 °C (250 °F).

It is essential to apply the protection cap to the motor before it goes into the autoclave.

12. MAINTENANCE

12.1– Fuse replacement

Technoimplant is protected by two fuses located in the power entry module.
To replace the fuses, proceed as follows.

- Unplug the unit from the mains.
- Extract the fuse drawer (fuse holder) with a screwdriver.
- Replace the fuse with one of the same type and value.

The fuse ratings are 0.8 Ampere for 230 V and 1.6 Ampere for 115 V, in each case of the T type (Time-delay or Time-lag).
The letter "F" or "T" represents the time-current characteristic of a Fast-acting or Time-delay fuse type. On Technoimplant a type "T" Time-lag fuse, called also Slo-Blo, should be used.

12.2 – Contrangle

Regarding the contrangle, please follow the manufacturer's instructions.

13. NOTE

Keep the instrument out of the reach of children. It is to be used exclusively for oral cavities as described in this text. The equipment may be used only in accordance with the specific instructions for its use. RTC Sistemi does not accept any responsibility for damages resulting from failure to comply with such instructions, or from uses other than those foreseen by the field of application for the product. The user is responsible for experimenting with materials for uses not explicitly described in these instructions. The descriptions and data reported herein are approximate and not binding. The contents of this user manual are subject to modifications without notice.

14.Warranty

- The duration of the warranty is one year from the date of the invoice.
- Any carrier's expenses are excluded from the warranty.
- The warranty shall be invalidated in case of repairs carried out by anybody not authorized by RTC SISTEMI.
- From the guarantee any defects shall be excluded which are:
- caused during transport,
- due to normal wear and tear,
- caused by fires or atmospheric events such as lightening discharge.

In case of breakdown of the equipment, please return it only to:

RTC SISTEMI Snc
Via A. FAULI, 60
59100 PRATO – ITALY

15. CE DECLARATION OF CONFORMITY

Manufacturer: RTC Sistemi snc
Via Anselmo Fauli, 60
I-59100 P R A T O (Italy)

Product: Micromotor for implantology identified with the name
"TECHNOIMPLANT Brushless"

Serial Number ….....

The above mentioned product conforms to the requirements of Directive CEE 93/42 and successive integrations relative to Medical Devices acknowledged in Italy with the Decree Law N° 46/97 and successive integrations, and to Directive 2007/47/CE acknowledged in Italy with Decree Law N° 37 of 25-01-2010.

This product is classified as Class IIa relative to the Directive CEE 93/42 and the Directive CEE 2007/47/CE, and has been certified by the CERMET notified body with identification number 0476.

In addition the device conforms to the following harmonized regulations:

CEI EN 60601-1: Electromedical Devices. Part 1: General safety rules.
EN 60601-1-2 Electromedical Devices. Part 1: General safety rules 2.
Electromagnetic compatibility EMC.

Prato (Italy) ….....

RTC Sistemi snc
(for the Executive Management)
Riccardo Rosati

Test Report **R-EM-244-0214-01A**

ANNEX 1. EMC TABLES TO BE INSERTED IN THE INSTRUCTION MANUAL.

Following, as a guide for the Manufacturer, are brought the **EMC** immunity and emission tables. These were filled according to clause 6 of EN 60601-1-2, based on test results. This information must be written in the documents accompanying the product.

Emissions		
Emission test	**Conformity**	**Electromagnetic Environment - guidance**
RF Emissions Cispr 11	Group 1	The appliance use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions Cispr 11	Class A	The appliance is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or its cables or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A Conforms	It is possible to use the device in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Conforms	

Immunity aspects			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**Test level EN 60601-1-2**	**Compliance Level**	**Electromagnetic environement - guide**
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Burst/Fast Transient EN 61000-4-4	±2kV power supply lines	±2kV power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Test Report **R-EM-244-0214-01A**

Immunity aspects			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**Test level EN 60601-1-2**	**Compliance Level**	**Electromagnetic environement - guide**
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	< 5% U_T (>95% dip in U_T) fo 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 seconds	< 5% U_T (>95% dip in U_T) fo 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field EN 61000-4-8	3 A/m	3 A/m	Magnetic power frequency fields should be that of a typical commercial or hospital environment.

Immunity aspects at r.f.			
The devices is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an electromagnetic environment.			
Immunity test	**Test level EN 60601-1-2**	**Compliance Level**	**Electromagnetic environement - guide**
RF conducted EN 61000-4-6	3 Veff from 150kHz to 80MHz	3 Veff from 150kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2 \cdot \sqrt{P}$ from 150kHz to 80MHz $d = 1,2 \cdot \sqrt{P}$ from 80 MHz to 800 MHz $d = 2,3 \cdot \sqrt{P}$ from 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m)
RF radiated EN 61000-4-3	3 Veff from 80MHz to 2,5GHz	3 Veff from 80MHz to 2,5GHz	
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:			

Test Report **R-EM-244-0214-01A**

Recommended separation distances between portable and mobile RF communications equipment and the Device			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance accordino to frequency of the transmitter (m)**		
	From 150kHz to 80MHz $d = 1,2 \cdot \sqrt{P}$	**From 80MHz to 800MHz** $d = 1,2 \cdot \sqrt{P}$	**From 800MHz to 2GHz** $d = 2,3 \cdot \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Notes: (1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			